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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,672	05/07/2002	Dan L. Eaton	P3230R1C001-168	7263
30313	7590 09/08/2004 EXAMINER			INER
	MARTENS, OLSON & B	ROMEO, I	ROMEO, DAVID S	
2040 MAIN STREET IRVINE, CA 92614			ART UNIT	PAPER NUMBER
,			1647	
			DATE MAILED: 09/08/2004	4

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/063,672	EATON ET AL.				
Office Action Summary	Examiner	Art Unit				
	David S Romeo	1647				
The MAILING DATE of this communication ap	pears on the cover sheet with the c	orrespondence address				
Period for Reply	VIO OET TO EVEIDE AMONTU	S) EDOM				
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a rep - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailine earned patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however, may a reply be tin  ly within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 09.5	September 2002.					
2a) This action is FINAL. 2b) ⊠ Thi	s action is non-final.					
3) Since this application is in condition for allows closed in accordance with the practice under						
Disposition of Claims						
4) Claim(s) 1-20 is/are pending in the application	1					
4a) Of the above claim(s) is/are withdra						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-10 and 14-20</u> is/are rejected.						
7)⊠ Claim(s) <u>11-13</u> is/are objected to.						
8) Claim(s) are subject to restriction and/	or election requirement.					
Application Papers						
9)⊠ The specification is objected to by the Examin	er.					
10)☐ The drawing(s) filed on is/are: a)☐ ac		Examiner.				
Applicant may not request that any objection to the						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)	1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/06) Paper No(s)/Mail Date 09/16/2002.	Paper No(s)/Mail D  5) Notice of Informal  6) Other:	Patent Application (PTO-152)				
LIC Division of Texture of Office						

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#### **DETAILED ACTION**

The preliminary amendment filed 09/10/2002 has been entered. Claims 1-20 are pending and being examined.

If a copy of a provisional application listed on the bottom portion of the accompanying Notice of References Cited (PTO-892) form is not included with this Office action and the PTO-892 has been annotated to indicate that the copy was not readily available, it is because the copy could not be readily obtained when the Office action was mailed. Should applicant desire a copy of such a provisional application, applicant should promptly request the copy from the Office of Public Records (OPR) in accordance with 37 CFR 1.14(a)(1)(iv), paying the required fee under 37 CFR 1.19(b)(1). If a copy is ordered from OPR, the shortened statutory period for reply to this Office action will not be reset under MPEP § 710.06 unless applicant can demonstrate a substantial delay by the Office in fulfilling the order for the copy of the provisional application. Where the applicant has been notified on the PTO-892 that a copy of the provisional application is not readily available, the provision of MPEP § 707.05(a) that a copy of the cited reference will be automatically furnished without charge does not apply.

## Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

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## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 14-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 9, does not reasonably provide enablement for nucleic acid molecules having a recited % identity to the genus of all nucleic acid molecules encoding the amino acid sequence of SEQ ID NO: 10, for the genus of all nucleic acid molecules encoding the amino acid sequence of SEQ ID NO: 10, for nucleic acid molecules that hybridize to the genus of all nucleic acid molecules encoding the amino acid sequence of SEQ ID NO: 10, for nucleic acid molecules having a recited % identity to SEQ ID NO: 9 without regard to the functional activity such nucleic acid molecules, or for nucleic acid molecules that hybridize to SEQ ID NO: 9 without regard to the functional activity of such nucleic acid molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The present application characterizes the PRO874 polypeptide (SEQ ID NO: 10) and polynucleotide (SEQ ID NO: 9) as follows:

[0036] FIG. 9 shows a nucleotide sequence (SEQ ID NO: 9) of a native sequence PRO874 cDNA, wherein SEQ ID NO: 9 is a clone designated herein as "DNA40621-1440".

[0037] FIG. 10 shows the amino acid sequence (SEQ ID NO: 10) derived from the coding sequence of SEQ ID NO: 9 shown in FIG. 9. Page 11.

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DNA40621-1440 is more highly expressed in normal lung than as compared to lung tumor. Example 18, Page 141.

Figure 10 also provides various structural features of the PRO874 polypeptide, presumably based on homology with domains of other known proteins. No further characterization is provided. Other than the hybridization language there are no functional limitations in the claims.

Only a limited number of polynucleotides encompassed by the genus of all nucleic acid molecules encoding the amino acid sequence of SEQ ID NO: 10 occur in nature. The specification only presents one such naturally occurring nucleic acid molecule, SEQ ID NO: 9. There are no working examples of polynucleotides that are not identical to SEQ ID NO: 9. The examiner is aware that working examples are not required. However, they are a factor to be considered. Yet the claims encompass any and/or all nucleic acid molecules encoding the amino acid sequence of SEQ ID NO: 10, having a recited % identity to the genus of all nucleic acid molecules encoding the amino acid sequence of SEQ ID NO: 10, hybridizing to the genus of all nucleic acid molecules encoding the amino acid sequence of SEQ ID NO: 10, having a recited % identity to SEQ ID NO: 9, and hybridizing to SEQ ID NO: 9.

The specification does not provide any information regarding the occurrence of these degenerate polynucleotides in nature and it is unpredictable which of those sequences, if any other than the native SEQ ID NO: 9 sequence, would be a native PRO polynucleotide encoding a native PRO polypeptide. The only obvious use of the degenerate polynucleotides is in the production of the encoded polypeptide. The only obvious use of the variant degenerate PRO polynucleotides would be in the production of

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variant PRO polypeptides. The only obvious use of the variant PRO polynucleotides that hybridize to the degenerate PRO polynucleotides would be in the production of variant PRO polypeptides.

With respect to variant PRO polynucleotides encoding variant PRO polypeptides the specification discloses:

[0208] "PRO variant polynucleotide" or "PRO variant nucleic acid sequence" means a nucleic acid molecule which encodes an active PRO polypeptide.

[0217] "In other embodiments, PRO variant polynucleotides are nucleic acid molecules that encode an active PRO polypeptide and which are capable of hybridizing, preferably under stringent hybridization and wash conditions, to nucleotide sequences encoding a full-length PRO polypeptide as disclosed herein. PRO variant polypeptides may be those that are encoded by a PRO variant polynucleotide."

With respect to PRO polypeptide variants the specification discloses:

[0258] "The variation allowed may be determined by systematically making insertions, deletions or substitutions of amino acids in the sequence and testing the resulting variants for activity exhibited by the full-length or mature native sequence."

It is noted that PRO874 is less than a full length polypeptide because the amino acid sequence of SEQ ID NO: 10 does not begin with an initiator methionine.

Accordingly, the specification discloses a less than full-length PRO polynucleotide encoding a less than full length PRO polypeptide. In addition, the specification does not disclose the activity exhibited by the full-length or mature native PRO polypeptide. If the specification does not disclose the full-length or mature native PRO polypeptide and does not disclose the activity exhibited by the full-length or mature native PRO polypeptide and if the claims are not limited by any functional limitation, then the specification has

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not enabled the screening of the resulting variants for activity exhibited by the full-length or mature native sequence. The examiner is aware that the present claims are directed to or encompass a polynucleotide. However, the only obvious use of the claimed polynucleotides, other than SEQ ID NO: 9, is in the production of the encoded 5 polypeptide. Furthermore, one skilled in the art recognizes that although structural similarity can serve to classify a protein as related to other known proteins this classification is insufficient to establish a function or biological significance for the protein because ancient duplications and rearrangements of protein-coding segments have resulted in complex gene family relationships. Duplications can be tandem or dispersed 10 and can involve entire coding regions or modules that correspond to folded protein domains. As a result, gene products may acquire new specificities, altered recognition properties, or modified functions. Extreme proliferation of some families within an organism, perhaps at the expense of other families, may correspond to functional innovations during evolution. See Henikoff (V), page 609, Abstract. Accordingly, one 15 skilled in the art would not accept mere homology as establishing a function of protein because gene products may acquire new specificities, altered recognition properties, or modified functions. Rather, homology complements experimental data accumulated for the homologous protein in understanding the homologous protein's biological role. Although, the presence of a protein module in a protein of interest adds potential insight 20 into its function and guides experiments, insight into the biological function of a protein cannot be automated. However, homology can be used to guide further research. See Henikoff (V), paragraph bridging pages 613-614, through page 614, paragraph bridging columns 1-2.

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As noted previously, other than the hybridization language there are no functional limitations in the claims. Although the specification discloses that DNA40621-1440 (SEQ ID NO: 9) is more highly expressed in normal lung than as compared to lung tumor (Example 18, Page 141), the specification provides no information regarding the level of expression, activity, or role in cancer of the PRO874 polypeptide. Further, differential tissue nucleic acid expression is not always correlated with protein levels. For example, Allman (U) discloses that germinal center B cells express dramatically more BCL-6 protein than resting B cells, despite similar BCL-6 mRNA levels in the two cell populations. Page 5257, paragraph bridging left and right columns. mRNA translation is regulated in many genes and can be mediated by binding of proteins to cis-acting RNA motifs in the untranslated regions of the mRNAs (paragraph bridging pages 5266-5267). Accordingly, the expression of SEQ ID NO: 9 in normal lung as compared to lung tumor does not provide a readily apparent use for the PRO polypeptide.

Furthermore, mere hybridization is not a substitute for producing a functional protein because of the number of nucleotide substitutions, insertions, an deletions encompassed by the hybridization language that encode a corresponding number of amino acid substitutions, insertions, deletions, and truncations.

Therefore, the claimed polynucleotides are not representative of the scope of enablement provided by the specification. The claim encompasses an unreasonable number of polynucleotides encoding inoperative polypeptides, which the skilled artisan would not know how to use. The skilled artisan would not know how to use the full scope of the degenerate polynucleotides or the full scope of the polynucleotides encoding non-identical polypeptides on the basis of teachings in the prior art or specification unless

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they encoded polypeptides that had the activity exhibited by the full-length or mature native sequence.

Moreover, there is a lack of predictability in the art. Predicting structure, hence function, from primary amino acid sequence data is extremely complex and there doesn't exist an efficient algorithm for predicting the structure of a given protein from its amino acid sequence alone. See Bowie (W) page 1306, column 1, full paragraph 1, and Ngo (X) page 433, full paragraph 1, and page 492, full paragraph 2.

For these reasons, which include the complexity and unpredictability of the nature of the invention, the one limited working example of the PRO874 polynucleotide SEQ ID NO: 9 and its single example of more high expression in normal lung than as compared to lung tumor example, the lack of direction or guidance for using polynucleotides encoding polypeptides that are not identical to the PRO874 polypeptide SEQ ID NO: 10, and the breadth of the claims for structure without function, it would require undue experimentation to use the invention commensurate in scope with the claims.

Claims 1-5, 14-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to or encompass nucleic acid molecules having a recited % identity to the genus of all nucleic acid molecules encoding the amino acid sequence of SEQ ID NO: 10, the genus of all nucleic acid molecules that hybridize to the genus of all

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nucleic acid molecules encoding the amino acid sequence of SEQ ID NO: 10, the genus of all nucleic acid molecules having a recited % identity to SEQ ID NO: 9, the genus of nucleic acid molecules that hybridize to SEQ ID NO: 9. The claims do not require that the polynucleotides possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polynucleotides that is defined only by some level of sequence identity that is either expressed or implied by the hybridization language.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity or hybridization. There is not even identification of any particular portion of the structure that must be conserved.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that

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[he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polynucleotides encoding polypeptides comprising the amino acid sequence of SEQ ID NO: 10, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8, 10, 14-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-6, 8, 10, 14-20 are indefinite over the

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recitation of "signal peptide" because there is a lack of antecedent basis in the specification for the signal peptide of SEQ ID NO: 10. It is further noted that PRO874 is less than a full length polypeptide because the amino acid sequence of SEQ ID NO: 10 does not begin with an initiator methionine. Thus, it is not even clear that the amino acid sequence of SEQ ID NO: 10 has a signal peptide. The metes and bounds are not clearly set forth.

Claims 1-6, 9, 10, 14-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-6, 9, 10, 14-20 are indefinite over the recitation of "the extracellular domain." There is a lack of antecedent basis in the specification for "the extracellular domain." Figure 10 discloses that SEQ ID NO: 10 possesses several transmembrane domains, and, thus, a corresponding number of extracellular domains, depending on how the polypeptide is arranged in the membrane. Thus, there is no one, single extracellular domain as is implied by the phrase "the extracellular domain." It is further noted that PRO874 is less than a full length polypeptide because the amino acid sequence of SEQ ID NO: 10 does not begin with an initiator methionine. Thus, even if one were to collectively construe all the extracellular domain" is disclosed. The metes and bounds are not clearly set forth.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. Claim 15 is indefinite over the recitation of "stringent conditions" because stringency varies according to the hybridization conditions and the particular hybrid under study. The specification fails to limit the definition of "stringent conditions." The metes and bounds are not clearly set forth.

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### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

. A person shall be entitled to a patent unless -

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 14-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Edwards (U. S. Patent No. 6312922).

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Edwards discloses an isolated nucleic acid molecule (SEQ ID NO: 141) that has a Best Local Similarity of 98.2% to SEQ ID NO: 9, as indicated below (Db = Edwards's nucleic acid molecule):

```
; Sequence 141, Application US/09247155A
     ; Patent No. 6312922
25
     US-09-247-155-141
       Query Match
                         42.7%; Score 412.6; DB 4; Length 891;
       Best Local Similarity 98.2%; Pred. No. 3.8e-110;
       Matches 445; Conservative
                              3; Mismatches
                                               Indels
30
     Qу
             514 ATCATGATCGCCATCTACGGGAAGAATTTCTGTGTCTCAGCCAAAAATGCGTTCATGCTA 573
                DЬ
              1 ATCATGATCGCCATCTACGGGAAGAATTTCTGTGTCTCAGCCAAAAATGCGTTCATGCTA 60
35
             574 CTCATGCGAAACATTGTCAGGGTGGTCGTCCTGGACAAAGTCACAGACCTGCTGCTGTTC 633
     Qу
                61 CTCATGCGAAACATTGTCAGGGTGGTCGTCCTGGACAAAGTCACAGACCTGCTGCTGTTC 120
     DЬ
             634 TTTGGGAAGCTGCTGGTGGTCGGAGGCGTGGGGGTCCTGTCCTTCTTTTTTTCTCCGGT 693
     Qy
40
                Db
             121 TTTGGGAAGCTGCTGGTCGGAGGCGTGGGGGGTCCTGTCCTTCTTTTTTTCTCCGGT 180
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	Qy	694 CGCATCCCGGGGCTGGGTAAAGACTTTAAGAGCCCCCACCTCAACTATTACTGGCTGCCC 753
	Db	
_	22	
5	Qy	754 ATCATGACCTCCATCCTGGGGGCCTATGTCATCGCCAGCGGCTTCTCAGCGTTTTCGGC 813
	Db	241 AYCATGACCTCCATCCTGGGGGCCTATGTCATCGCCAGYGGCTTCTTCAGCGTTTTCGGC 300
10	Qy	814 ATGTGTGGGACACGCTCTTCCTCGCTTCCTGGAAGACCTGGAGCGGAACAACGGCTCC 873
10	Db	
	Qy	874 CTGGACCGGCCCTACTACATGTCCAAGAGCCTTCTAAAGATTCTGGGCAAGAAGAACGAG 933
15	Db	360 CTGGA-CGGCCCTACTACATGTCCAAGAG-CTTCTAAAGATTCTGGGCAAGAAGAACGAG 417
	Qy	934 GCGCCCCCGGACAACAAGAAGAGGAAGAAGTGA 966
20	Db	
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Edwards nucleic acid molecule was first disclosed in U. S. Application No. 60/081,563, as indicated in TABLE I. Edwards disclosure is tantamount to the disclosure of a nucleic acid molecule that the complement of Edwards's nucleic acid molecule. In view of the Best Local Similarity of 98.2% to SEQ ID NO: 9, the complement of Edwards's nucleic acid molecule would hybridize to SEQ ID NO: 9 (a nucleic acid molecule encoding SEQ ID NO: 10) even under stringent conditions, in the absence of evidence to the contrary.

#### Conclusion

Claims 11-13 are objected to as being dependent upon a rejected base claim.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571)272-0961.

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ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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DAVID ROMEO PRIMARY EXAMINER ART UNIT 1647

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DSR SEPTEMBER 6. 2004